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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,933	12/30/2003	David J. Parins	1001.1676101	1930

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EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,933	PARINS ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,59 and 60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,59 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to an amendment filed March 14, 2006. Claims 1-22 and 59-60 are pending. Claims 23-58 and 61-62 are pending. No new claim has been added. Claims 10 and 16 have been amended.

Claim Objections

2. The objections are withdrawn due to amendments.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-7, 12-17, 21-22 and 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al. (US Patent No. 6,673,025).

In regards to claim 1, Richardson et al. discloses a guidewire 140, comprising:

a core member 141 having a proximal end and a distal end;

a tubular member 156 having a proximal end and a distal end, the tubular member 156 disposed about and connected to the distal end of the core member 141, the distal end of the tubular member 156 extending distally beyond the distal end of the core member 141; and

a coil member 151 connected to the tubular member 156 (see fig. 20).

In regards to claim 2, Richardson et al. discloses a guidewire wherein the coil member 151 includes a distal end and a proximal end, and wherein the distal end of the coil member 151 extends distally beyond the distal end of the tubular member 156 (see fig. 20).

In regards to claim 3, Richardson et al. discloses a guidewire wherein the proximal end of the coil member 151 is positioned distal of the distal end of the core member 141 (see fig. 20).

In regards to claim 4, Richardson et al. discloses a guidewire wherein the proximal end of the tubular member 156 fits over the distal end of the core member 141 (see fig. 20).

In regards to claim 5, Richardson et al. discloses a guidewire wherein the proximal end of the coil member fits over the distal end of the tubular member (see fig. 20).

In regards to claim 6, Richardson et al. discloses a guidewire further including a polymer sheath 157 disposed about the coil member 151, the tubular member 156, and at least a portion of the core member 141 (see fig. 20).

In regards to claim 7, Richardson et al. discloses a guidewire wherein the polymer sheath 157 is disposed over all of the core member 141 (see fig. 20).

In regards to claim 12, Richardson et al. discloses a guidewire wherein the tubular member 156 has a hemispherical cross section (see fig. 20).

In regards to claim 13, Richardson et al. discloses a guidewire wherein the tubular member 156 has a circular cross section (see fig. 20).

In regards to claim 14, Richardson et al. discloses a guidewire comprising:

a core member 141 including a proximal portion having a proximal end and a distal portion having a distal end; and

a distal assembly (151, 156) including a tubular member 156 having an inner surface adapted for connection to the distal portion of the core member 141, and an outer surface, and a coil member 151 connected to the tubular member 156;

wherein the distal assembly (151, 156) is connected to the distal portion of the core member 141 such that a portion of the distal assembly extends distally beyond the distal end of the core member 141 (see fig. 20).

In regards to claim 15, Richardson et al. discloses a guidewire wherein the distal assembly is connected to the distal portion of the core member 141 such that a portion of the tubular member 156 extends distally beyond the distal end of the core member 141 (see fig. 20).

In regards to claim 16, Richardson et al. discloses a guidewire wherein the coil member 151 includes a distal end and a proximal end, and wherein the distal end of the coil member 151 extends distally beyond the distal end of the tubular member 156 (see fig. 20).

In regards to claim 17, Richardson et al. discloses a guidewire further including a polymer sheath disposed about the coil member 151, the tubular member 156, and at least a portion of the core member 141 (see fig. 20).

In regards to claim 21, Richardson et al. discloses a guidewire wherein the tubular member 156 has a hemispherical cross section (see fig. 20).

In regards to claim 22, Richardson et al. discloses a guidewire wherein the tubular member 156 has a circular cross section (see fig. 20).

In regards to claim 59, Richardson et al. discloses a medical device comprising:

an elongated shaft 141 including a proximal portion having a proximal end and a distal portion having a distal end; and

a distal assembly including a tubular member 156 and a ribbon or wire 151 connected to and extending distally of the tubular member 156; wherein the distal assembly is connected to the distal portion of the elongated shaft 141 such that a portion of the distal assembly (151, 156) extends distally beyond the distal end of the elongated shaft 141 (see fig. 20).

In regards to claim 60, Richardson et al. discloses a medical device wherein the ribbon or wire is a coiled ribbon or wire 151 (see fig. 20).

Richardson et al. disclose a guidewire comprising a plurality of polymer layers substantially arranged in the same manner as Applicant's device with the exception that Applicant has explicitly identified an inner polymer layer as "a tubular member" (see Applicant's drawings, figs. 3-4 and Richardson et al., figure 20). As such, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a guidewire similar to that of Richardson et al. with a plurality of polymer layers of different kinds arranged in a multitude of ways about the core wire and the coil since such a modification would amount to a design choice. It has previously been held that changing aesthetic design is not patentable--See In re Seid, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

5. Claims 8, 11, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al. (' 025) in view of Palmer et al. (US Patent No. 6,544,231).

Richardson et al. discloses a guidewire 10, as described above, that teaches all the limitations of the claims except Richardson et al. does not teach the process of laser welding or soldering. However, Palmer et al. disclose a medical instrument wherein a coil is bonded to a metallic tubular structure through laser welding (see column 4/lines 16-18). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a connected apparatus similar to that of Richardson et al. with a connecting process similar to that of Palmer et al. in order to tightly fuse metal elements together.

6. Claims 9-10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al. (' 025) in view of Palmer et al. ('231) further in view of Cook et al. (US Patent No. 5,213,111).

Richardson et al. as modified by Palmer et al. discloses a guidewire, as described above, that teaches all the limitations of the claim except Richardson et al. as modified by Palmer et al. does not teach connecting the tubular member through crimping. However, Cook et al. disclose a guidewire wherein a coil member 151 is connected to a core member through crimping (see column 3/lines 13-16). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a guidewire similar to that of Richardson et al. as modified by Palmer et al. with a connecting process similar to that of Cook et al. in order to hold the elements together in a friction-fit fashion.

7. Claims 1-4, 13-16, 22, and 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Toledo (US Patent No. 5,065,769) in view of Buchbinder et al. (US Patent No. 4,757,827).

In regards to claim 1, De Toledo discloses a guidewire 10, comprising:

a core member 42 having a proximal end and a distal end;

a tubular member 52 having a proximal end and a distal end, the tubular member 52 disposed about and connected to the distal end of the core member 42, the distal end of the tubular member 52 extending distally beyond the distal end of the core member 42; and,

a coil member (12, 14) (see fig. 1).

In regards to claim 2, De Toledo discloses a guidewire 10 wherein the coil member (12, 14) includes a distal end and a proximal end, and wherein the distal end of the coil member (12, 14) extends distally beyond the distal end of the tubular member 52 (see fig. 1; column 3/lines 44-45, 51; column 4/line 9).

In regards to claim 3, De Toledo discloses a guidewire 10 wherein the proximal end of the coil member 52 is positioned proximate to or distal of the distal end of the core member 42 (see fig. 1).

In regards to claim 4, De Toledo discloses a guidewire 10 wherein the proximal end of the tubular member 52 fits over the distal end of the core member 42 (see fig. 1).

In regards to claim 13, De Toledo discloses a guidewire 10 wherein the tubular member 52 has a circular cross section (see fig. 1).

In regards to claim 14, De Toledo discloses a guidewire 10 comprising:

a core member 42 including a proximal portion having a proximal end and a distal portion having a distal end; and

a distal assembly including a tubular member 52 having an inner surface adapted for connection to the distal portion of the core member 42, and an outer surface;

wherein the distal assembly is connected to the distal portion of the core member 42 such that a portion of the distal assembly extends distally beyond the distal end of the core member 42 (see fig. 1).

In regards to claim 15, De Toledo discloses a guidewire 10 wherein the distal assembly is connected to the distal portion of the core member 42 such that a portion of the tubular member 52 extends distally beyond the distal end of the core member 42 (see fig. 1).

In regards to claim 16, De Toledo discloses a guidewire 10 wherein the coil member (12, 14) includes a distal end and a proximal end, and wherein the distal end of the coil member (12, 14) extends distally beyond the distal end of the tubular member 52 (see fig. 1; column 3/lines 44-45, 51; column 4/line 9).

In regards to claim 22, De Toledo discloses a guidewire 10 wherein the tubular member 52 has a circular cross section (see fig. 1).

In regards to claim 59, De Toledo discloses a method of making a medical device 10 comprising: an elongated shaft 42 including a proximal portion having a proximal end and a distal portion having a distal end; and a distal assembly including a tubular member 52 and a ribbon or wire (12, 14); wherein the distal assembly is connect to the

distal portion of the elongated shaft 42 such that a portion of the distal assembly extends distally beyond the distal end of the elongated shaft 42 (see fig. 1).

In regards to claim 60, De Toledo discloses a method of making a medical device 10 wherein the ribbon or wire (12, 14) is a coiled ribbon or wire (see fig. 1; column 3/lines 44-52).

De Toledo teaches a system, as described above, teaches all the limitations of the claims except that De Toledo does not teach system wherein the tubular member is connected to the coil member. However, Buchbinder et al. disclose(s) a system wherein the tubular member 44 is connected to the coil member 49 (see fig. 3; column 4/lines 20-24). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of De Toledo with a tubular member connected to the coil member similar to that of Buchbinder et al. in order to form a continuous lumen for the guidewire (see Buchbinder et al., column 3/lines 5-8).

8. Claims 8, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Toledo ('769) in view of Buchbinder et al. ('827) further in view of Palmer et al. (US Patent No. 6,544,231).

De Toledo as modified by Buchbinder et al. discloses a guidewire 10, as described above, that teaches all the limitations of the claims except De Toledo as modified by Buchbinder et al. does not teach the process of laser welding or soldering. However, Palmer et al. disclose a medical instrument wherein a coil is bonded to a metallic tubular structure through laser welding (see column 4/lines 16-18). It would

have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a connected apparatus similar to that of De Toledo as modified by Buchbinder et al. with a connecting process similar to that of Palmer et al. in order to tightly fuse metal elements together.

9. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Toledo ('769) in view of Buchbinder et al. ('827) in view of Palmer et al. ('231) further in view of Cook et al. (US Patent No. 5,213,111).

De Toledo as modified by Buchbinder et al. as further modified by Palmer et al. discloses a guidewire, as described above, that teaches all the limitations of the claim except De Toledo as modified by Buchbinder et al. as further modified by Palmer et al. does not teach connecting the tubular member through crimping. However, Cook et al. disclose a guidewire wherein a coil member is connected to a core member through crimping (see column 3/lines 13-16). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a guidewire similar to that of De Toledo as modified by Buchbinder et al. as further modified by Palmer et al. with a connecting process similar to that of Cook et al. in order to hold the elements together in a friction-fit fashion.

Response to Arguments

10. Applicant's arguments, see amendment, filed March 14, 2006, with respect to the rejection(s) of claim(s) 1, 14 and 59 under 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. From the Applicant's remarks filed March 14, 2006, it is construed that Applicant's use of the limitation

"connected to" is intended to mean "joined or fastened together: united." As such, upon further consideration, a new ground(s) of rejection is made in view of Richardson et al. (see rejections supra) and De Toledo in view of Buchbinder et al. (see rejections supra).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 5,063,935 to Gambale discloses a catheter guidewire with varying radiopacity at its distal end.

US Patent No. 5,217,026 to Stoy et al. discloses a guidewire with lubricious surface and method of fabrication.

US Patent No. 5,365,944 to Gambale discloses a guidewire extension with self-latching detachable connector.

US Patent No. 5,993,424 to Lorenzo et al. discloses a guidewire having a distal tip that can change its shape within a vessel.

US Patent No. 5,234,437 to Sepetka discloses a detachable pusher-vasocclusion coil assembly with threaded coupling.

US Patent No. 5,452,726 to Richardson et al. discloses an intravascular guide wire and method for manufacture thereof.

US Patent No. 5,211,636 to Mische discloses a steerable infusion guide wire having state-of-the-art handling characteristics for ease of positioning a variety of catheters.

US Patent No. 5,452,726 to Burmeister et al. disclose an intravascular guide wire and method for manufacture thereof.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT

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